

PAIN RELIEF SIGNATURE CARE- menthol 10.5% spray

Better Living Brands

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Menthol 10.5%.....

Purpose

Topical Analgesic

Uses Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame.

When using this product • avoid contact with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to the irritated skin • do not bandage • wash hands after use with cool water • do not use with heating pad or device

Stop use and ask a doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately

Directions • Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age: Consult physician.

Inactive ingredients Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomile Recutita Flower Extract, Dimethyl Sulfone, Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

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Quality Guaranteed

Compare to Biofreeze® active ingredient*

NDC 00000-000-00

Cold Therapy Pain Relief Spray

10.5% MENTHOL Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints



NET WT 3 OZ (85 g)

*This product is not distributed by Performance Health, LLC., makers of the registered trademark Biofreeze®.



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UPC PLACEMENT

PAIN RELIEF SIGNATURE CARE

menthol 10.5% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	10.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

CHAMOMILE (UNII: FGL3685T2X)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-333-03	85 g in 1 CAN; Type 0: Not a Combination Product	03/30/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2018	

Labeler - Better Living Brands (009137209)

Registrant - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(21130-333) , label(21130-333)

Revised: 1/2018

Better Living Brands